User Fee Performance Goals[1] and Implementation Status Summary

Review Goals (NDAs, BLAs, PLAs)

- Review and act on 90 percent of standard applications within 10 months – phased in over 5 years
- Review and act on 90 percent of priority original NDA/BLA applications within 6 months
- Review and act on 90 percent of standard efficacy supplements within 10 months – phased in over 5 years
- Review and act on 90 percent of priority efficacy supplements within 6 months
- Review and act on 90 percent of manufacturing supplements within 6 months; review and act on 90 percent of manufacturing supplements requiring prior approval within 4 months – phased in over 5 years
- Review and act on 90 percent of Class I resubmissions within 2 months – phased in over 5 years
- Review and act on 90 percent of Class II resubmissions of original NDAs and BLAs within 6 months

Results Achieved

- FDA met all but one of our review goals for NDAs, BLAs, and PLAs received in FY 1998. Results for FY 1999 receipts will be available in December 2000.
- *Resubmissions: Final guidance for industry published May 14, 1998.*
- *Efficacy supplements; standards for review: Final guidance for industry published May 15, 1998.*
- *Average time from submission of an application to approval has dropped from about 30 to 12 months. (FDA 1999 Risk Management Report)*

[1] Performance goals were stated in a letter from Secretary Shalala to Senator Jeffords dated November 12, 1997.

- *There has been an increase of almost 40% in the number of new products approved per year, from a yearly average of 70 to 97 applications. (FDA 1999 Risk Management Report)*

- *Time to market for new drugs has dropped by 18%. (Tufts Center for Study of Drug Development, July 1999)*

Meeting Management Goals

- Schedule meetings about PDUFA products and notify the requestor in writing of the date, time, and place of the meetings within 14 days of receipt of meeting requests from the sponsor. Meetings should be scheduled to occur:

  -- Type A Meetings: within 30 days of receipt of the meeting request
  -- Type B Meetings: within 60 days of receipt of the meeting request
  -- Type C Meetings: within 75 calendar days of receipt of the meeting request

- Official minutes of the meeting should be available to the sponsor within 30 calendar days after the meeting.

- These goals are phased in over 5 years

Results Achieved

- *Meetings for PDUFA products: Final guidance published March 7, 2000.*

- *In 1999, we met all of our meeting management goals.*

Clinical Hold Goals (INDs)

- CDER and CBER should respond to a sponsor's complete response to a clinical hold within 30 days of receipt of the complete response.

- This goal is phased in over 5 years

Results Achieved

- *Revisions to the Agency's requirements on investigational new drugs (21 CFR 314.42) published December 14, 1998 (direct final rule). Final guidance for industry published May 14, 1998.*

- *In 1999, we met our clinical hold goal.*

Dispute Resolution Goals

- CDER and CBER should respond to requests for dispute resolution about procedural or scientific matters regarding PDUFA products within 30 days of receipt of the appeal

- Responses should be verbal (followed by written confirmation within 14 calendar days of the verbal notification) or written and ordinarily should be to grant or deny the appeal

- If further data or information are needed to resolve the dispute, or if the matter is taken to an advisory committee, the person responsible for the appeal should respond within 30 calendar days of receiving the information

- These goals are phased in over 5 years

Results Achieved

- *Final guidance* for industry published March 7, 2000.

- *In 1999, we met our dispute resolution goals.*

Special Protocol Assessment Goals

- Upon specific request by a sponsor, FDA will evaluate carcinogenicity protocols, stability protocols, and Phase 3 protocols for clinical trials that will form the primary basis of an efficacy claim to assess whether the design, conduct, and analyses are adequate to meet scientific and regulatory standards.

- Within 45 days of receipt of the protocol and specific questions, FDA will provide a written response to the sponsor.

- If the Agency agrees to the design, execution, and analyses proposed in the protocols reviewed under this process, the Agency will not later alter its perspective on the issues unless public health concerns unrecognized at the time of protocol assessment under this process are evident.

- These goals are phased in over 5 years.

Results Achieved

- *Draft guidance for industry published February 9, 2000.*
- *In 1999, we met our special protocol assessment goals.*

Electronic Applications and Submissions

- FDA will update its information management infrastructure to allow, by FY 2002, the paperless receipt and processing of INDs and marketing applications.

Results Achieved

We are on track to meet the 2002 goals for electronic submission of marketing applications and INDs.

- *We have issued guidance documents on general issues and on specific issues regarding electronic submissions of NDAs and marketing applications for biological products.*
- *We have been receiving and reviewing electronic submissions for drugs since February 1999 and for biologics since June 2000.*
- *In addition to guidance on electronic marketing applications and INDs, we are developing guidance for providing electronic postmarketing safety reports, drug master files, annual reports, advertising and promotional material, drug registration and listing, and investigator information.*

Simplification of Action Letters (NDAs, BLAs, PLAs)

- CDER and CBER will amend their regulations to provide for the issuance of an approval or a complete response action letter at the completion of a review cycle.

Results Achieved

- *Amendments to CDER regulations (21 CFR 314.100) under development*
- CBER had no regulations. They have been issuing complete response letters since 1996.

Sponsor Notification of Deficiencies (NDAs, BLAs, PLAs)

- CBER and CDER intend to submit deficiencies to applicants in a discipline review letter when each discipline has finished its initial review of its section of a pending application

Results Achieved

- *Sponsor notification of deficiencies: Draft guidance for industry explaining information request and discipline review letters published August 17, 1999.*

Exemptions From User Fees
Summary

Special Populations

- *Pediatrics* (0 - 16 years of age): Supplements solely for a new pediatric indication or a modification of an existing pediatric indication are exempt from paying an application fee.

  (Under PDUFA 1, pediatric supplements were not exempt from application fees.)

- *Orphans*: Designated orphan drug applications and supplements are exempt from application fees if the 2 conditions below are met.[1] Orphan drug applications and supplements are not exempt if they contain proposed indications that are not designated as orphan indications. Orphan products are not automatically exempt from product or establishment fees. They may qualify for a waiver under the regular waiver criteria.

  1. The drug must be designated as one for a rare disease or condition under section 526 of the Act
  2. The application may not include an indication that is not for a rare disease or condition.

  (Under PDUFA 1, orphan drug applications and supplements were not exempt from application fees.)

- *State or Federal Government Entities:* State and Federal government entities are not assessed application, product, or establishment fees if their drug products are not distributed commercially.

User Fee Collection Process
Summary

What are the specific fees?

- An **application fee** is assessed upon the submission of most new human drug applications (orphan drugs are exempt).

  FY 2000 application fee amounts are as follows:

  -- *Original application requiring clinical data = $285,740*
  -- *Original application requiring no clinical data = $142,870*
  -- *Supplemental application requiring clinical data = $142,870*
  (supplements for new pediatric uses are exempt)

- An **annual product fee** is assessed on all approved, drug-listed human drugs (generic applications[1] are exempt).

  FY 2000 product fee is: $19,959

- An **annual establishment fee** is assessed on a manufacturing site if a user fee liable product is manufactured at that site. In cases when more than one applicant uses a site to manufacture user fee liable products, the establishment fee is divided evenly among the applicants manufacturing there.

  FY 2000 establishment fee is $141,971

How are fees calculated each year?

- Fees are calculated based on a number of factors, including, for example, the number of applications the Agency received during the previous fiscal year; the number of applications the Agency anticipates during the coming year; the number of products and establishments billed in the previous year; inflation factors; and other factors.

What happens if the appropriate fee isn't received?

- The application is in arrears, and the review clock stops.

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[1]Generic applications approved under 505(b)(2) and (505)(j)

- No NDAs, BLAs, PLA's, or supplements can be accepted from that applicant until all fees owed are received in full.

- Once an applicant has paid its bills, submissions can be received again. Performance goal dates are calculated based on the date the full payment is received.

- Interest penalties and administrative cost penalties are assessed for each month that the fees are overdue. Interest rate penalties are determined by the U.S. Treasury Department.

What happens if an application is refused for filing?

- If the application is withdrawn before filing or filing is refused, 75% of the fee is refunded. We keep 25% for work done on the application in making a filing determination.

- If the applicant resubmits the application, it must pay the full fee again.

How does FDA collect the fees?

- Application fees are to be paid upon submission of an application or supplement. Fee rates for the fiscal year are published in a Federal Register notice each December for the coming year.

- Product and establishment fees are collected through annual invoices.

Are there any refunds?

- Yes, refunds can be made depending on the situation. For example, if an application is submitted and then receives orphan designation, a fee will be refunded. But the applicant must request the refund within 180 days of the date the fee is due.

Waiver and Reduction of Fees

When can the FDA waive or reduce a fee?

- **To protect the public health** - Fees may be waived or reduced if the product is intended to protect the public health *and* a waiver is necessary to continue an activity that protects the public health or the fee is a significant barrier to the entity's ability to develop, manufacture, or market the product.

- **To reduce a significant barrier to innovation** - Fees may be waived or reduced if the product is innovative *and* the fee is a significant barrier to the entity's ability to develop, manufacture, or market the product.

- **When the fees exceed the costs** - Fees may be waived or reduced if fees owed by the applicant exceed the anticipated present and future standardized costs of FDA's process for reviewing all of the applicant's human drug applications and supplements (including INDs).

- **When there is an inequitable assessment of fees between applicants submitting 505(b)(1) applications and those submitting 505(b)(2) applications** - Fees may be waived or reduced if one applicant did not have to pay a fee on an application and the second applicant submits an application with the same active ingredient.

- **If a small business applicant submits its first human drug application** - Application fees may be waived if the applicant has fewer than 500 employees, including employees of its affiliates (as determined by the Small Business Administration) *and* the applicant is submitting its first human drug application to FDA for review. Fees for subsequent applications and supplements submitted by the small business will be assessed appropriate user fees.

  (New waiver provision under PDUFA 2.)

PRESCRIPTION DRUG USER FEE ACT III (PDUFA III)
QUESTIONS AND ANSWERS

1. Why is FDA holding this public meeting?

The Food and Drug Administration (FDA) is holding this public meeting to hear the views of its many stakeholders about the PDUFA program. The current coverage of the Act (PDUFA II) expires at the end of fiscal year (FY) 2002, and the fees and resources provided under that Act will also expire without further legislation.

FDA is now considering what features it should advocate in proposing new or amended authorizing legislation. To assure that the PDUFA program continues to serve the needs of the public, FDA is holding this meeting to hear from all interested persons. The public's views are important to the Agency.

2. What is the Prescription Drug User Fee Act (PDUFA) and what does it do?

In 1992, Congress passed the Prescription Drug User Fee Act (PDUFA). PDUFA authorized FDA to collect fees from companies that produce certain human drug and biological products. The original PDUFA had a five-year life; it ended in 1997, the same year Congress passed the FDA Modernization Act (FDAMA). Part of FDAMA included an extension of PDUFA for an additional five years (PDUFA II).

The original intent of PDUFA was to provide FDA with additional revenue so it could hire more reviewers and support staff and upgrade its information technology to speed up the application review process for human drugs and biological products without compromising review quality. In exchange for these resources, FDA agreed to certain performance goals designed to speed the review process without sacrificing quality.

3. What products are covered by PDUFA? Are foods and cosmetics included? What about medical devices or animal drugs?

Only certain human drugs and certain biologics are covered by PDUFA. No user fees are assessed for generic drugs, blood products, foods, cosmetics, medical devices or animal drugs.

4. How has FDA benefited from PDUFA?

PDUFA has had a dramatic and undeniable impact on the drug review process. Total resources for drug review activities have increased from $120 million in 1992, before PDUFA was enacted, to an estimated $325 million in FY 2002, about half of which will come from fees paid by industry. These resources allowed FDA to increase its drug and biological review staff by almost 60% between 1993 and 1997, adding about 660 staff-years to the program by 1997. By

the end of PDUFA II in 2002, FDA expects to have added another 313 staff-years of effort to this program. These additional staff, and resources to support them, has enabled FDA to review new drug and biologic applications more rapidly without compromising review quality.

5. What are the sources of industry funding under PDUFA? Do companies literally pay for a favorable review?

Industry pays three types of fees: (1) application fees for the submission of certain human drug or biological applications; (2) annual establishment fees paid for each establishment that manufactures prescription drugs or biologics, and (3) annual product fees assessed on certain prescription drug and biological products.

Companies do not pay for a favorable review. FDA performance goals direct FDA to complete a review and take an action which may be an approval letter, an approvable letter or a not approvable letter.

6. Since the companies are paying for the review of their product, do they have any influence over the review or do they receive any special privileges or considerations?

No, companies do not have any influence over FDA's review of their marketing applications (NDAs, BLAs, or PLAs) nor do they receive any special privileges or considerations. As stated above, PDUFA provides additional revenue so FDA can hire more reviewers and support staff and upgrade its information technology to speed up the application review process for human drug and biological products without compromising review quality.

7. How does FDA decide which division gets the financial resources provided by the PDUFA fees?

All organizational units that are involved in the premarket review of certain human drugs receive PDUFA funding. Certain units, such as the Office of Generic Drugs and the Office of Blood do not receive resources provided by user fees.

8. Are there FDA divisions that do not receive PDUFA fees? How does that affect those that are left out?

By law, PDUFA fees may only be used for specific costs related to pre-market review of drug applications. Accordingly, only those organizations that are involved with the process for the review of human drugs receive PDUFA funding. Other organizations do not receive PDUFA funding, e.g., those involved with postmarketing review and generic drug review. Resources needed to perform these nonPDUFA activities, supplied in most cases totally from appropriations, are diminishing in real terms as pay costs increase each year without a corresponding increase in appropriations.

9. What impact has the PDUFA program had on the workload of the agency's review divisions?

PDUFA has increased the total resources for certain drug review activities enabling FDA to respond more rapidly to new drug and biologic applications. However, PDUFA performance goals and standards have resulted in increased pressure to meet deadlines, and have increased tracking and reporting requirements.

10. Is FDA satisfied with the way the PDUFA program is performing?

We have been pleased with the increase in drug review resources and resulting improvements in efficiency in the drug approval process without decreasing the quality of our review. However, FDA continues to struggle with the inequities of the PDUFA vs nonPDUFA activities. The resources devoted to PDUFA related activities continues to increase while real resources needed for nonPDUFA activities continue to shrink. Assuring that enough appropriated dollars are spent on the process for the review of human drug applications to meet the requirements of PDUFA, and at the same time spending our resources in a way that best protects health and safety of the American people is becoming increasingly difficult.

11. What are the limitations of PDUFA?

There are 3 specific requirements on spending identified in PDFUA. If any of these 3 requirements are not met, the authority to collect and spend fees disappears. These requirements are: (1) require FDA's overall appropriations grow at the same rate as the rest of the government; (2) require FDA spending from appropriations on drug review each year is equal to or greater than the spending amount, for this purpose in FY 1997, adjusted for inflation; (3) require FDA's use of fees be provided for in specific amounts in FDA's annual appropriation acts.

Of these three requirements, the second is the most difficult to meet. The second requirement was envisioned to operate in equilibrium with the first requirement – in an environment where FDA's total resources kept up with inflation, and therefore having appropriations for drug review grow with inflation would be equitable. However, FDA's core programs, including drug reflew activities funded from appropriations, have not been given appropriation increases to cover the cost of mandated annual federal pay raises since 1994. As a result staffing for almost all of FDA's core programs, e.g., routine food plant inspections, blood safety, medical device regulation, over-the-counter drugs, generic drugs, and postmarket review, have shrunk. But to assure that appropriated spending on PDUFA grows to meet the inflation demands of PDUFA, even more funds have been taken from these other core programs and added to drug review to assure the second requirement is met.

Since 1992, the percent of FDA funding that has been used to support drug review has increased from 17% to 28%, while funding for all other FDA activities has declined from 83% to 72%.

12. What improvements would FDA like to see in the PDUFA program?

The agency has not taken any position yet of specific improvements we would like to see in the PDUFA program and statute. We are holding the September 15, public meeting to share some of our views about what is working well with PDUFA and what is not, and to hear from our many stakeholders on their views about this program. Only after hearing the views of our stakeholders at this meeting and reviewing any comments submitted will the agency decide on specific changes it would like to advocate.

13. Does FDA believe that industry provides too much money to the review program?

No. The funds provided by industry to assist the expeditious review program under PDUFA were negotiated with industry and approved through Congress. However, as the amount of fees spent on drug review approaches and may surpass 50% of the total drug review spending, we feel compelled to raise this issue. In Australia and the United Kingdom all funds for drug regulation come from industry fees. In Canada about 70% of funds for drug review currently come from fees. We are seeking stakeholder views on this public policy issue.

14. Does industry now provide all financial support for FDA's review programs?

No. PDUFA authorizes FDA to collect fees from the pharmaceutical industry to augment FDA's base resources. FDA must spend at least as much from appropriated funds from the review of human drug applications as it spent in FY 1997, adjusted for inflation. Currently about half of drug review funding is supplied from appropriations.

15. Has industry's financial support for FDA's review programs increased, decreased or remained the same since PDUFA began? If it's changing, why is it changing?

Industry's financial support has increased substantially over the course of PDUFA. Prior to 1993, no fees were paid by industry—all drug review costs were funded from appropriations. In the first few years the fees from PDUFA were phased in—from $36 million in the first year, 1993, to $87.5 million in 1997, the last year under PUDFA I. With PDUFA II the fee schedule was changed in order to provide additional resources for challenging new goals, and to include automatic annual adjustments for inflation and workload increases. In 1998, the first year of PDUFA II, FDA collected $117 million, and by FY 2002 we expect collections to increase to about $162 million, and spending from fees to be about $171 million—utilizing funds collected but not spent in earlier years. These increases were supported by both industry and FDA when PDUFA II was enacted, to assure that fee revenues kept pace with the increasing federal payroll costs and changes in review workload.

16. Some critics say that because industry provides some of the funding for FDA's review programs, that the agency has lowered the scientific standards used to evaluate the safety and effectiveness of a new therapeutic. Is that true?

No. FDA continues to approve drugs based on data that shows the safe and effective use of the drug.

17. The critics also say that FDA has sped up its review time so much that products are being approved too quickly and that important safety problems are being missed as a result. Is that true? Are drugs and biologics being reviewed too fast?

This isn't true. When Dr. Henney first became FDA Commissioner, she established a Task Force to look into exactly this question. The Task Force evaluated whether the heightened sense of time pressure on Agency review teams had reduced the quality of FDA's reviews or caused poor decision making.

The Task Force undertook a major evaluation of the Agency's premarketing and postmarketing review processes and relevant quality control systems. In addition, it evaluated how often unanticipated serious adverse events were being identified from 1990 to 1998 and compared these numbers to those collected by a 1990 General Accounting Office (GAO) report on serious adverse events for drugs reviewed prior to 1990.

The Task Force found that, despite shortened FDA review times, the rate of market withdrawals for safety reasons has remained relatively unchanged over the decades. FDA's premarketing review processes are successfully identifying the serious risks associated with using medical products just as well as in previous decades.

18. Has FDA observed any increase in drug withdrawals because of unexpected adverse events once a drug or biologic goes on the market?

No. The FDA performed an analysis of market withdrawals over the last 2 decades, to evaluate any possible relationship between the speed of review and the need to withdraw an approved drug. The data did not suggest a relationship between the time required to review an application properly and the likelihood of product withdrawals because of adverse events.

19. What FDA functions are not supported by PDUFA funding that probably should be supported by the extra resources?

There are many functions not currently supported by PDUFA funding. For example, postmarketing surveillance of a drug, review of generic drug applications, review of certain blood products, review of chemistry supplements, tracking activities associated with the

performance and standard goals, and certain compliance activities are not supported by PDUFA funding. We are interested in views of our stakeholders about whether any, some, or all of these should be paid from fee revenue.

20. Is post-market surveillance for unexpected adverse events covered by PDUFA?

No. PDUFA specifies that fees are to be spent for the preapproval drug review process only. This excludes any post-approval work, i.e., monitoring adverse drug reactions after a product is marketed.

21. Has industry been satisfied with the PDUFA program and the way it works?

We believe the industry has generally been satisfied. However, the purpose of the stakeholders meeting is to gather information from all parties on the positive and negative attributes of PDUFA.

22. Have patient groups been satisfied with the speed up in FDA reviews for new drug and biologic treatments?

We do not know from a global perspective if patient groups are satisfied with PDUFA. One of the purposes of the Stakeholders meeting is to gather information from all parties on the positive and negative attributes of PDUFA.

23. Would FDA prefer to have its review program completely funded by Congress instead of receiving funding from industry?

Congress approves all funding for FDA activities. This includes both the base funding from appropriations and the amount of funds that may be collected under PDUFA. We are open to alternate approaches as long as they do not force us to comprise the quality of our review and allow us to maintain current staffing and operations levels.

A list of questions that we are asking interested parties to address at this meeting follows:

1. Since 1993 FDA has been receiving fees for the review of certain human drug and biological products. As a result, FDA has implemented management improvements that have substantially decreased the time for new drug review and made new medications available to the public faster. Do you view this as a benefit of the user fee program that should be maintained in the future? What are some of the other benefits that you think are important? How do you think the program can be strengthened? In addition, what do you see as the downside of a regulatory agency like FDA collecting user fees and what remedies would you propose for the future?

2. Should we continue to have performance goals for the drug and biological review process? If so, how should goals be determined?

3. If user fees fund FDA's drug and biological review processes, what percentage of the program's costs should be covered by fees, and how should those fees be used? The following table shows the percent of drug and biological review spending funded by industry fees since the beginning of PDUFA in 1993:

TABLE 1.

	1993	1994	1995	1996	1997	1998	1999
Fee percent	7%	24%	36%	36%	36%	40%	43%

The percent paid from fee revenues is currently estimated to exceed 50% of FDA's spending on drug review by 2002.

The following table shows the approximate percent of costs of overall drug regulation paid from industry fees in some other countries:

TABLE 2.

Country	Australia	Canada	United Kingdom
Fee percent	100%	70%	100%

4. Should fees collected from industry be used to pay for other costs FDA incurs to assure that drugs in the American marketplace are safe and effective? Such additional costs might include monitoring adverse drug reactions, monitoring drug

Application Fees

Applications	Specific Application Requirements?	Clinical Data Required for Approval?	FY 2000 Fee Amount	Exemptions
Original NDA - 505(b)(1)	1) Not Submitted by a State or Federal Government entity for a drug that is not distributed commercially 2) Not a Large Volume Parenteral (LVP) application approved prior to 9/1/1992	yes	$285,740	Orphan Designated
Original NDA - 505(b)(1)	Same as above	provided by reference[1] or not needed for review	$142,870	Orphan Designated
Original NDA - 505(b)(2)	Must be an application for a molecular entity which is an active ingredient or an indication for a use that has not been approved under section 505(b)	yes	$285,740	Orphan Designated
Original NDA - 505(b)(2)	Same as above	reference or no	$142,870	Orphan Designated
PLA or BLA	1) Not a whole blood or blood component for transfusion 2) Not a bovine blood product for topical application licensed before 9/1/1992 3) Not an allergenic extract 4) Not an in vitro diagnostic biologic product licensed under section 351 of PHS Act 5) Not for further manufacturing use only 6) Not submitted by a State or Federal Government entity for a drug that is not distributed commercially	yes	$285,740	Orphan Designated

[1]Clinical data provided by reference to another FDA reviewed application

Applications	Specific Application Requirements?	Clinical Data Required for Approval?	FY 2000 Fee Amount	Exemptions
Supplement to NDA, PLA or BLA	Must meet same requirements as original NDA, PLA, or BLA	yes	$142,870	1) Orphan Designated 2) New Pediatric Use
ANDA - 505(j)	None	N/A	no fee	N/A
INDs	CDER or CBER applications	N/A	no fee	N/A

Product and Establishment Fees

Application Type	Product Fee Requirements	FY 2000 Product Fee	FY 2000 Establishment Fee Requirements	FY 2000 Establishment Fee[1]
Approved Product from 505(b)(1) application or supplement	1) Drug Listed[2] 2) No 505(b)(2) or 505(j) competition	$19,959	1) Product Fee Assessed 2) Drug manufactured during fiscal year	$141,971
Approved Product from 505(b)(1) application or supplement	1) Drug Listed 2) No 505(b)(2) or 505(j) competition	$19,959	1) Product Fee Assessed 2) Drug **not** manufactured during fiscal year	$0
Approved Product from 505(b)(2) application	N/A	No product fee	N/A	no establishment fee
Approved Product from PLA/BLA or supplement	Drug Listed	$19,959	1) Product Fee Assessed 2) Biologic manufactured during fiscal year	$141,971
Approved Product from PLA/BLA or supplement	Drug Listed	$19,959	1) Product Fee Assessed 2) Biologic **not** manufactured during fiscal year	$0
Approved Product from 505(j) application	N/A	no fee	N/A	no fee

1. Establishment fee is shared equally by all User Fee Applicants manufacturing product at that individual site regardless of number of products manufactured at the site.

2. Drug Listed under section 510 of the Federal Food, Drug, and Cosmetic Act

JANE E. HENNEY, M.D.

Commissioner of Food and Drugs
Food and Drug Administration

Dr. Henney began her tenure as Commissioner of the Food and Drug Administration (FDA) in November of 1998. Prior to that, she served as the first Vice President of the University of New Mexico Health Sciences Center from 1994 to 1998. Before joining the University, Dr. Henney served as the Deputy Commissioner for Operations at FDA from 1992 to 1994. Dr. Henney's other past academic administrative positions have included Vice Chancellor for Health Programs and Policy at the University of Kansas, and Acting Director of the University of Kansas Mid America Cancer Center from 1985 to 1992. She also served as Interim Dean of the School of Medicine at the University of Kansas from 1987 to 1989. From 1976 to 1985, Dr. Henney held various positions at the National Cancer Institute (NCI) of the National Institutes of Health. From 1980-1985, Dr. Henney was Deputy Director of the NCI.

In addition to being an active member of many professional societies, Dr. Henney has been the President of the United States Pharmacopeial Convention, a member of the Advisory Committee to the Director for the National Institutes of Health, a member of the National Advisory Research Resources Council, and a member of the American Cancer Society National Board of Directors. She has served as a member of the Board of Directors of the Lovelace Respiratory Institute, the Kansas Health Foundation, and the Kansas State University Cancer Center. Dr. Henney also has served on an Advisory Committee for The Commonwealth Fund and as a consultant to the W.K. Kellogg Foundation. She has also served as a member of the Board of Trustees at Manchester College.

Dr. Henney is a graduate of Indiana University School of Medicine and Manchester College. She completed her medical internship at St. Vincent's Hospital, and her residency at Georgia Baptist Hospital. Dr. Henney was a Fellow in Medical Oncology at M.D. Anderson Hospital and Tumor Institute, and completed graduate medical work at the Cancer Therapy Evaluation Program at NCI. She has also completed management training at the John F. Kennedy School of Government at Harvard University.

In addition to other distinguished honors, Dr. Henney was recently given an Honorary Fellowship from the American College of Healthcare Executives. She also received the Indiana University Medical School Distinguished Alumni Award in 1998, the Manchester College Alumni Award in 1996, the M.D. Anderson Cancer Center Distinguished Alumnus Award, and was a member of the Leadership New Mexico Inaugural Class in 1996-1997. Dr. Henney received the Public Health Service Commendation Medal in 1979 and 1981, and the Commissioner's Special Citation in 1994. Dr. Henney has also received the Jacobs Institute's Excellence in Women's Health Award, the Public Health Leadership Award from the National Organization for Rare Disorders, and the George Crile Award from the International Platform Association.

LINDA A. SUYDAM, D.P.A.

Senior Associate Commissioner
Food and Drug Administration

As Senior Associate Commissioner, Dr. Suydam is responsible for the development and implementation of processes to implement change and develop new regulatory strategies for the Food and Drug Administration (FDA) to efficiently and effectively operate within a global economy. Dr. Suydam advises the Commissioner on all matters concerning strategic management and oversees all activities within the Office of the Commissioner. One of her principal responsibilities was the development of the initial Agency plan required under Section 406(b) of the Food and Drug Administration Modernization Act of 1997.

Prior to rejoining the Agency in July 1998, Dr. Suydam was the Associate Vice President for Planning and Development of the Health Sciences Center (HSC) at the University of New Mexico in Albuquerque. The HSC is the only comprehensive patient care, education, and research health care organization in New Mexico. Dr. Suydam was responsible for strategic and facilities planning, marketing, public relations, development, research coordination, the animal research facility and the HSC Library.

Dr. Suydam's career at the FDA prior to 1995 spanned 17 years of more progressive responsibility beginning in the Bureau of Medical Devices as a program analyst and including six years as the executive officer for the Center for Devices and Radiological Health; two years as the Associate Commissioner for Operations in the Office of the Commissioner and culminating as the Interim Deputy Commissioner for Operations from April 1994 until September 1995. During her FDA career, Dr. Suydam received numerous awards including the Department of Health and Human Services Secretary's Award for Distinguished Service, the Public Health Service Superior Service Award, two individual FDA Awards of Merit and many group awards.

Prior to joining the FDA in 1978, Dr. Suydam held progressively responsible professional positions in the public and private sector as a counseling administrator, social work supervisor and caseworker. Dr. Suydam holds a BA from the College of New Jersey, an MA from George Washington University, an MPA from the University of California (USC), and a Doctorate in Public Administration from USC. She is married to Dr. Gerald L. Barkdoll and resides in Rockville, Maryland.

JANET WOODCOCK, M.D.

Director, Center for Drug Evaluation and Research
Food and Drug Administration

Janet Woodcock, M.D., is the director, Center for Drug Evaluation and Research, CDER). She coordinates the activities of the largest center in the Food and Drug Administration, with more than 1,700 employees. CDER assures that safe and effective drugs are available to the American public.

During her tenure, Dr. Woodcock has piloted CDER through a sea of regulatory change. When selected for the director's position in 1994, Dr. Woodcock was given the task of leading the Center to meet stringent performance goals under the Prescription Drug User Fee Act (PDUFA). Under Dr. Woodcock's stewardship, FDA has enhanced the delivery of new drugs to Americans while preserving the Agency's high standards for quality, efficacy and safety. To date, the Center has cut new drug review time nearly in half, while the number of new drugs approved each year has

doubled. As a result of its PDUFA success, FDA was named winner of the Innovations in American Government Award. Considered to be among the nation's most prestigious public-service prizes, the award recognizes governmental initiatives that provide creative solutions to pressing social and economic problems. FDA was lauded for its accomplishments related to the U.S. drug approval process.

A primary goal of Dr. Woodcock's tenure has been opening up the "black box" of FDA drug regulations, making regulatory decision-making open and transparent to the public. This has been accomplished by 1) relaying CDER's regulatory procedures and policies to the public by publishing over 100 "guidances" that describe regulatory standards, 2) developing an unprecedented degree of participation of consumer and patient representatives in CDER processes, and 3) creating a Center web site and posting extensive information, including drug reviews and consumer information.

A current initiative involves transferring all CDER information processes to electronic format. At present, adverse drug event reports and many regulatory submissions are being filed electronically.

Prior to joining CDER, Dr. Woodcock was director of the Office of Therapeutics Research and Review, Center for Biologics Evaluation and Research (CBER). There she oversaw approval of the first biotechnology-based treatments for multiple sclerosis and cystic fibrosis.

An internist/rheumatologist, she joined FDA in 1985. She served as director of the Division of Biological Investigational New Drugs in CBER from 1988-1992 and was acting deputy director of the CBER in 1991-92.

Dr. Woodcock has earned three Awards of Merit, two Commendable Service Awards, two Commissioner's Special Citations, and a Presidential Rank Meritorious Executive Award. She also received the Nathan Davis Award from the American Medical Association in 1999.

Dr. Woodcock received her M.D. from Northwestern University Medical School in 1977. She received her undergraduate degree from Bucknell University. She has held faculty appointments at Pennsylvania State University and the University of California at San Francisco. She lives in Maryland with her husband and is the mother of two daughters.

KATHRYN C. ZOON, Ph.D.

Director, Center for Biologics Evaluation and Research
Food and Drug Administration

Dr. Zoon became director of the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration in March 1992. Dr. Zoon was formerly the Director of the Division of Cytokine Biology in CBER, where she was actively involved with regulatory issues related to cytokines, growth factors and studies on interferon purification, characterization and interferon receptors. Dr. Zoon worked at NIH from 1975 to 1980, with Nobel Prize Laureate Christian B. Anfinsen on the production and purification of human interferons. She continued her work in interferon and reviewed cytokine products when she joined the FDA in 1980. She received her B.S. degree, cum laude, in chemistry from Rensselaer Polytechnic Institute in 1970 and was granted a Ph.D. in biochemistry from The Johns Hopkins University in 1975.

Dr. Zoon is an editor of the Journal of Interferon Research and the author of numerous scientific papers on nterferons. She serves on the Foundation for Advanced Education in the Sciences (FAES) Board of Directors as first vice president. She is a member of the NIH Scientific Directors, chair of the FDA Senior Biomedical Research Service (SBRS) Credentialing Committee, as well as the FDA representative to the DHHS SBRS Policy Board. She has received numerous awards, including BioPharm Person of the Year Award 1992, the NIH Lectureship 1994, Sydney Riegelman Lectureship 1994, Genetic Engineering News (GEN) Award 1994 for streamlining and improving the regulatory process for biologics and biotechnology products, the Meritorious Executive Rank Award 1994 for sustained superior performance in revitalizing and reorganizing the Center for Biologics Evaluation and Research to meet the challenges of new responsibilities and new technologies, National Cancer Patients "Grateful Patients Award" 1996, Rensselaer Polytechnic Institute Alumni Association Fellows Award 1997, the Secretary's Award for Distinguished Service 1998 as a member of the FDA Reform Legislation Working Group, and the 1999 Johns Hopkins University Delta Omega Alpha Chapter's 75th Anniversary Outstanding Member Award.

ABBEY MEYERS

President
The National Organization for Rare Disorders

Abbey S. Meyers is a founder of the National Organization for Rare Disorders (NORD), a coalition of national voluntary health agencies and a clearinghouse for information about these little known illnesses. Mrs. Meyers is President of NORD, a former member of the NIH Recombinant DNA Advisory Committee (RAC), which oversees human gene therapy experiments in the United States, a former member of the National Commission on Orphan Diseases, and a former member of the FDA Biological Response Modifiers Committee. Mrs. Meyers continues to serve on the FDA's Xenotransplantation Subcommittee, and as an ad hoc advisor for the FDA and NIH. She is the recipient of the FDA Commissioner's Special Citation for Exceptional Dedication and Achievements on Behalf of All People Afflicted with Rare Disorders, and the Department of Health and Human Services Award for Public Health Service for Exceptional Achievements in Orphan Drug Development. Mrs. Meyers holds an Honorary Doctorate from Alfred University in New York. She is considered the primary consumer leader responsible for passage of the Orphan Drug Act.

JEFF BLOOM

Patient Representative

Jeff Bloom is a long time AIDS advocate and volunteer at several of the nation's leading AIDS advocacy organizations. He has worked with the National Association of People with AIDS, AIDS Action Council, and Project Inform.

A long-term survivor of AIDS, Mr. Bloom attended the University of Maryland at College Park. After graduating in 1981, he embarked on a business career that included more than 10 years as a Chief Executive Officer and Chief Financial Officer of a multimillion dollar audio-video corporation. Complications from HIV, infection of the spinal cord, caused Mr. Bloom to retire from corporate life in August 1994 and to embark on his current path of volunteerism. He has served as a Patient Representative on the Food and Drug Administration's Antiviral Drugs Advisory Committee.

CARL F. DIXON

Executive Director
Kidney Cancer Association

Carl F. Dixon, the President and Executive Director of the Kidney Cancer Association, holds B.A. and B.S. Degrees, magna cum laude, from Illinois Wesleyan University. In 1970, he was awarded the Edward R. Murrow Fellowship to the Fletcher School of Law and Diplomacy and completed an M.A. He received a J.D. from the Law School of the University of Chicago in 1974.

Prior to joining the Kidney Cancer Association, Mr. Dixon practiced law in Chicago, concentrating on the areas of nonprofit corporation and association law. He has a long history of service to voluntary health organizations, serving for over 20 years on various boards of the American Lung Association in Ohio and Illinois. He is also a director of the Chicago Opera Theater, and a member of the Board of Visitors of Illinois Wesleyan. He serves as Alumni Association president for Illinois Wesleyan, and is a member of the Board of the National Health Council.

MYRL WEINBERG, CAE

President,
National Health Council

Myrl Weinberg is president of the National Health Council, an umbrella organization that has served as the place where "the health community meets" for 80 years. The Council's 115+ members are national health-related organizations. Its goals are to promote quality health care for all people, to promote the importance of medical research, and to promote the role of voluntary health agencies, also called patient-based groups. The Council's core constituency is its voluntary health agencies—such as American Diabetes Association, Lupus Foundation of America, and Arthritis Foundation—that represent more than 100 million people with chronic diseases and/or disabilities. The Council's member organizations also include professional associations, other nonprofit organizations with an interest in health, managed care companies and their umbrella organization, and pharmaceutical and biotechnology companies.

Ms. Weinberg's career has focused on health, medical research, long-term care, social security and related issues that affect persons with chronic diseases and/or disabilities. She was honored to be selected to serve on the Congressionally mandated Institute of Medicine committee created to assess how research priorities are established at the National Institutes of Health. Before joining the Council, Ms. Weinberg held numerous managerial positions at the American Diabetes Association, including serving as Vice President for Corporate Relations and Public Affairs. Ms. Weinberg also has a long history of board and committee service.

Under Ms. Weinberg's leadership, the National Health Council actively supported the reauthorization of the Food and Drug Administration Modernization and Accountability Act of 1997, which has benefited patients across the country by providing them timely access to innovative and potentially life-saving therapies. Ms. Weinberg pursued advanced graduate study at Purdue University. She holds an M.A. in Special Education from George Peabody College and a B.A. in Psychology from the University of Arkansas.

CINDY PEARSON

Executive Director
National Women's Health Network

Cindy Pearson is the Executive Director of the National Women's Health Network. Founded in 1975, the Network was the first feminist health group to utilize a national membership in support of D.C.-based health activism. The Network's goal is to bring the voices of women everywhere decisions are being made that affect women's health. The Network testifies before Congress and the FDA, speaks out at scientific meetings, publicizes issues through the media, networks individual activists and other local and national groups working on women's health, and mobilizes its constituency to influence decisions made by federal regulatory agencies.

Cindy has worked at the Network since 1987. In addition to representing the Network in the media and to the government, Cindy has served on the Boards of the Reproductive Health Technologies Project, the National Breast Cancer Coalition, the Campaign for Women's Health, the D.C. Women's Council on AIDS, the National Action Plan on Breast Cancer and the Advisory Board of the Boston Women's Health Book Collective. Cindy has received the Special Service Award from the National Association for Women's Health, the Commissioner's Special Citation from the Food and Drug Administration, the Margaret Sanger Award from the Federation of Feminist Women's Health Centers and the Susan B. Anthony Award from San Diego County N.O.W.

Cindy is also one of the five co-authors of Taking Hormones and Women's Health, the Network's book about the medicalization of menopause and alternative approaches. Prior to working at the Network, Cindy served as the director of Colorado NARAL and Womancare Clinic in San Diego, California.

LARRY D. SASICH, Pharm. D., M.P.H., FASHP

Pharmacist
Public Citizen

Dr. Sasich received his Bachelor of Science in pharmacy from Idaho State University and Pharm. D. from the University of the Pacific. He completed a American Society of Hospital Pharmacist's accredited residency in nuclear pharmacy at the University of New Mexico and a Master of Public Health degree with an emphasis in epidemiology at the George Washington University in Washington D.C. He has taught drug information both in the U.S. and overseas and is currently with Public Citizen's Health Research Group in Washington D.C. and is co-author of Worst Pills, Best Pills - a consumer's guide to avoiding drug induced death or illness.

BRETT KAY

Program Associate for Health Policy
National Consumers League

Mr. Kay serves as the Program Associate for Health Policy at the National Consumers League and works on issues ranging from food safety, health care and managed care issues, to pharmaceutical care. Mr. Kay serves on the Food and Drug Administration's Consumer Consortium, which is

charged with selecting consumer representatives to serve on the FDA's Advisory Boards, which oversee the approval of pharmaceuticals and medical devices. Mr. Kay also serves on the American Pharmaceutical Association's Self-Care Panel, which is charged with developing treatment protocols for pharmacists for over-the-counter drugs. He was recently selected to sit on the Commission for Certification for the American Nurses Credentialing Center. Mr. Kay serves on the Conference for Food Protection, which develops model food codes for retail establishments. He also represents the League in various coalitions on food safety and health care issues.

Mr. Kay received a B.A. in Comparative Literature from Brandeis University in 1992 and his Masters Degree in Public Policy, with a concentration on health policy, from the Johns Hopkins University in Baltimore, Maryland, in May of 1997.

ARTHUR AARON LEVIN, M.P.H

Director
Center for Medical Consumers

Arthur Aaron Levin, MPH, is Director of the Center for Medical Consumers in New York City. Founded in 1976, the Center has focused on providing consumers with the tools to make informed decisions about their health care. Towards that end, the Center established one of the first medical libraries organized for the public. In addition the Center publishes HealthFacts, a monthly newsletter which uses medicine's own literature and experts to critique common medical practice and advice.

Mr. Levin's special interests as a public advocate have focused on some of the following policy issues: the role of government in the oversight and surveillance of health care industries, systems and professionals; the rights of consumers to make fully informed choices; the need for transparent information systems that empower consumers as well as facilitate the work of health professionals and organizations.

Mr. Levin serves on the New York State Department of Health Work Group that has revamped the state's hospital incident reporting system. He is a current member of the Institute of Medicine's Quality of Health Care in America Committee whose first report, "To Err Is Human" was published last December.

Mr. Levin also co-chairs the FDA Consumer Consortium, which nominates consumer representatives for Drug and Device advisory committees. He serves as a guest expert presenting the consumer viewpoint at FDA Advisory Committee meetings. He has served on two consecutive State Task Forces focusing on clinical guidelines, technology assessment, quality concerns and performance reporting and has recently begun reporting state-collected hospital and physician volume information in New York State through the Center's web page.

Mr. Levin received his B.A. from Reed College in philosophy and his MPH in health policy and administration from Columbia University School of Public Health. He is an adjunct instructor at Columbia University's School of Public Health and has taught in the graduate health policy program at the New School.

LARRY R. VERSTEEGH, Ph.D.

Vice President
Procter & Gamble Pharmaceuticals

Larry R. Versteegh, Ph.D. is Vice President, Regulatory and Clinical Development at Procter & Gamble Pharmaceuticals where he has global responsibility for Regulatory Affairs, Clinical Development and Medical Affairs, Biometrics, Data Management, and Clinical Quality Assurance.

Dr. Versteegh has more than 20 years experience in the pharmaceutical industry including positions with Bristol-Myers, G. D. Searle, and Pharmacia prior to joining Procter & Gamble Pharmaceuticals. He is a member, and past chairman, of the Regulatory Affairs Coordinating Committee of the Pharmaceutical Research and Manufacturers of America and a member of the Regulatory Advisory Board of the Centre for Medicines Research, International. Dr. Versteegh earned his B.A. degree in Chemistry from Central College (Iowa) and received a Ph.D. in Biochemistry from Iowa State University.

CARL B. FELDBAUM

President
Biotechnology Industry Organization

Carl B. Feldbaum is president of the Biotechnology Industry Organization (BIO) which represents more than 900 companies, academic institutions and state biotechnology centers in 49 states and 26 nations.

Mr. Feldbaum came to Washington, D.C. in 1973 as an assistant special prosecutor for the Watergate special prosecution force to work with Archibald Cox to investigate and prosecute the Watergate scandal. Prior to his appointment as president of BIO, Mr. Feldbaum was chief of staff to Senator Arlen Specter (R-PA) of Pennsylvania. He was also president and founder of the Palomar Corporation, a national security "think tank" in Washington, D.C. Before founding Palomar Corporation, Mr. Feldbaum was assistant to the Secretary of Energy, and served as the Inspector General for defense intelligence in the U.S. Department of Defense.

In 1979, Mr. Feldbaum was awarded the Distinguished Civilian Service Medal from Defense Secretary Harold Brown. He received the Christopher Medal for his book "Looking the Tiger in the Eye: Confronting the Nuclear Threat," which was also designated by the New York Times as a notable book of the year for 1988. Mr. Feldbaum received a bachelor's degree in Biology from Princeton University and his law degree from the University of Pennsylvania Law School.

CHRISTOPHER L. PELLONI

Vice President of Research & Development
TEVA Pharmaceuticals USA

Chris Pelloni is currently the Vice President of Research and Development at TEVA Pharmaceuticals USA, located in North Wales, Pennsylvania.

Chris joined TEVA 3 years ago as Senior Director of Pharmaceutical R&D, and presently is the Vice President of R&D with responsibilities that now include Pharmaceutical R&D, Analytical R&D and Regulatory Affairs.

Prior to joining TEVA, Chris was with Geneva Pharmaceuticals, Inc., a subsidiary of Novartis, where he spent 12 of his 28 years with Geneva heading up the New Product Development Group. Chris has had a variety of responsibilities including commercial product technical services, active pharmaceutical ingredient sourcing, business development support, patent litigation technical support, and manufacturing management experience.

Chris has earned a Bachelor of Science in Business Administration (1986) and a Master of Business Administration (1989) from Regis University in Denver, Colorado. He is Co-chair of the GPhA Science Committee and belongs to the American Association of Pharmaceutical Scientists.

ROBERT S. MILANESE

President

National Association of Pharmaceutical Manufacturers

Robert S. Milanese is President and Chief Executive Officer of the National Association of Pharmaceutical Manufacturers (NAPM), the voice of the U.S. generic drug industry. As the frontline trade organization representing generic pharmaceutical manufacturers, distributors and their suppliers, NAPM's first priority is a total commitment to providing safe, effective, affordable drugs to U.S. consumers. NAPM is dedicated to protecting and expanding a thriving, freely competitive pharmaceutical marketplace in which consumers can benefit from high-quality, low-cost alternatives to brand name drugs.

Mr. Milanese is recognized as a leading industry strategist in combating anti-competitive measures by innovator (brand name) drug companies and in helping to shape legislative and regulatory changes that influence the marketplace. He has testified before numerous congressional committees on legislation impacting the manufacture and distribution of generic drugs, and is a highly regarded advocate on the issues of drug affordability and consumer choice. In 1998, Mr. Milanese was instrumental in forming the Coalition for Affordable Pharmaceuticals (CAP), a group established by three industry trade associations to promote alternatives to high-priced brand name drugs.

Under Mr. Milanese's leadership, NAPM has called on President Clinton to include a preference for generic drugs in his proposed Medicare prescription drug benefit. He is currently directing industry efforts to prevent new patent extensions for eight brand name drugs, which would cost consumers over $11 billion. In 1999, Mr. Milanese led a selected group of industry executives in advising the U.S. Trade Representative on the potential impacts of the Free Trade Area of the America Agreement (FTAA) on generic pharmaceuticals. He is also one of the five coordinating members of the International Generic Pharmaceutical Alliance, which includes member companies from Canada, the European Union and the U.S.

Over more than a decade, Mr. Milanese has established NAPM as the leading sponsor of professional conferences and workshops, routinely attracting senior faculty from the Food and Drug Administration, as well as senior executives from every segment of the generic pharmaceutical industry. Elected officials from both houses of Congress often serve as keynote speakers at NAPM

meetings. Mr. Milanese is sought as a commentator for print and broadcast reporting on pharmaceutical pricing, and as an authoritative source for industry reviews. He is also regularly consulted by FDA regulators, congressional staffers and others.

Mr. Milanese is Vice Chairman of the Board of the National Council on Patient Information and Education (NCPIE), and a member of the Associations Council of the National Association of Manufacturers. Prior to joining NAPM in 1988, Mr. Milanese was Managing Director of Perlite Institute Inc., an international trade association serving the perlite industry worldwide. During his 18-year tenure, that organization grew to become a leader in international standards development for insulation and building materials.

Mr. Milanese holds an MBA in Management and a B.S. degree in Mechanical Engineering from New York University. He is married with four children and resides in Shoreham, New York, where he volunteers as a coach and serves on the Area Committee for Suffolk County Special Olympics.

JOSEPH W. CRANSTON, Ph.D.

Director, Science Research, and Technology
American Medical Association

Joseph W. Cranston, Ph.D., is the Director, Division of Science, Research, and Technology, and Program Director for Drug Policy at the American Medical Association (AMA). Dr. Cranston has an undergraduate degree in pharmacy and received a Ph.D. in pharmacology from the University of Michigan School of Medicine in 1972. He then completed a two-year Damon Runyon postdoctoral fellowship in the Department of Developmental Biology and Cancer at the Albert Einstein College of Medicine. Dr. Cranston spent the next seven years in basic research (nucleic acid enzymology and tumor biomarkers) both at a medical school (University of Louisville) and a research center (NCI - Frederick Cancer Center). He left basic research in 1981 when he joined the AMA as a Senior Scientist in the Department of Drugs (now Program on Drug Policy). Until 1995, Dr. Cranston worked on the AMA's DRUG EVALUATIONS compendium, focusing on antimicrobial therapy.

In 1988, he became Department Director and since then, he has played a major AMA staff role in drug policy development for the association. He has worked on multiple issues, including drug utilization review (DUR), drug formularies and substitution, medication errors, FDA reform, off-label uses, Y2K and pharmaceuticals, direct-to-consumer advertising, Internet prescribing and health professional and patient information. Dr. Cranston has been the AMA representative to the Board of the National Council on Patient Information and Education (NCPIE) since 1994. He served as Secretary and Vice Chair of the NCPIE Board in 1995 and 1996, respectively. He also has been the AMA's delegate to the United States Pharmacopeial Convention (USP) since 1990, and recently represented the AMA on the National Association of Boards of Pharmacy's (NABP) working group for the Verified Internet Pharmacy Practice Sites (VIPPS) program.

JOHN A. GANS, Pharm.D.

Executive Vice President
American Pharmaceutical Association

John A. Gans is the Executive Vice-President and Chief Executive Officer of the American Pharmaceutical Association (APhA). Since 1970, he has been professionally affiliated with the Philadelphia College of Pharmacy and Science, where he earned his pharmacy degree in 1966 and his doctorate in pharmacy in 1969. He also served on the faculty from 1980-88. From 1988 until his appointment to APhA in May 1989, Dr. Gans served as the Dean of the School of Pharmacy.

Dr. Gans began his career in 1966 as a community pharmacist in Broomall, Pennsylvania. During 1967-68, Dr. Gans served a residency at the Hospital of the University of Pennsylvania. Following his residency, he became Assistant Director of Pharmacy at the Hospital of the University of Pennsylvania and held that position from 1968-70. From 1974 to 1985, he served as the Managing Director of Pharmaservices, a consultant firm to nursing homes. Dr. Gans' research interests included the original work in the development of total parenteral nutrition in dogs and humans for which he received a research award in 1972 from the American Society of Hospital Pharmacists.

Dr. Gans has served as the Chairman of the Delaware Valley Regional Poison Control Program, which established a 24-hour regional poison control center in 1985. In 1980-81, he served as President of the Pennsylvania Society of Hospital Pharmacists and, in 1986-87, as President of the American Society of Hospital Pharmacists. Other honors include the 1997 PCP&S Alumni Award and the 1998 Harvey A. K. Whitney Lecture Award presented by the American Society of Health-system Pharmacists.

Dr. Gans' commitment to the profession of pharmacy is not limited to the United States. He has been actively involved in international pharmacy for many years. He served as the Pan American Federation of Pharmacy Secretary-General (1991-1994) and as Vice President for North America since 1994, having been re-elected in 1997 for a second three-year term. He has served as an FIP Council member since 1989, and as a member of the Working Group on FIP Public Policy in 1995. He was most recently elected as a Vice President to the FIP Bureau in 1998.

RICHARD ALAN LEVINSON, M.D., D.P.A.

Associate Executive Director
American Public Health Association

Dr. Levinson currently serves as the Associate Executive Director of the American Public Health Association. He received a bachelor's degree in liberal arts and a master's degree in microbiology from the University of Chicago, an MD degree from the University of Illinois at Chicago, and a Doctor of Public Administration from George Washington University. He completed an internal medicine residency and a fellowship in gastroenterology at the University of Iowa.

His professional positions included serving at the Veterans Administration Central Office in Washington, DC from 1970 to 1981. While with the VA, Dr. Levinson served in a series of managerial positions including chief of Allied Health Education, and Deputy Assistant Chief Medical Director for Professional Services. He next served as Assistant Director of the Duval County (FL) Health Department and following that as the Director of the Pinellas County (FL) Health

Department. His next position was that of Director of the Detroit (MI) Health Department. Following that he was Chief of Preventive Health Services in the DC Department of Health. He assumed his current position in 1997.
Dr. Levinson has served as a faculty member at the medical schools of the Universities of Utah and Florida, and as an adjunct professor in the School of Public Health of the University of South Florida. He is currently an Adjunct Associate Professor of Health Sciences at the George Washington University School of Public Health. In his present position, Dr. Levinson is responsible for the scientific and professional activities of the American Public Health Association.

KENNETH I. KAITIN, Ph.D.

Director
Tufts Center for the Study of Drug Development

Dr. Kaitin is Director of the Tufts Center for the Study of Drug Development, an academic drug policy research group providing strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of the drug development process. He is also Assistant Professor of Pharmacology and Experimental Therapeutics at Tufts University School of Medicine. Dr. Kaitin conducts research, lectures, and writes on pharmaceutical development, regulation, and public policy. He has written extensively on factors that contribute to the slow pace and high cost of pharmaceutical R&D and the impact of regulatory and legislative initiatives to speed new drug development and approval.

Dr. Kaitin has provided public testimony before the U.S. Congress in hearings on FDA reform, and has worked closely with the U.S. Council on Competitiveness. Dr. Kaitin is a former President of the Drug Information Association (1997-98), and he serves on the faculty of the European Center for Pharmaceutical Medicine. He is a member of the American Society for Clinical Pharmacology and Therapeutics, the New York Pharma Forum, and Regulatory Affairs Professionals, and he is on the editorial boards of the American Journal of Therapeutics, Clinical Research and Regulatory Affairs, and the Drug Information Journal. Dr. Kaitin received a B.S. from Cornell University and an M.S. and Ph.D. in pharmacology from the University of Rochester.

STUART WALKER, B.SC., PH.D.

Director
Center for Medicine's Research, International

Professor Stuart R. Walker, B.Sc., Ph.D. (Lond), Cchem., C.Bcol., F.R.Sc, FIBiol, FInstD., FRCPath, is the Director of CMR International in the U.K. aan Honorary Professor of Pharmaceutical Medicine, University of Wales, Cardiff. He spent ten years at London University which included lectureships in biochemical pharmacology at St. Mary's Hospital Medical School and in clinical pharmacology at the Cardiothoracic Institute in London. This was followed by eight years with Glaxo Group Research in the U.K. where he had international responsibility for several of their clinical research programs.

His current research interests include studies concerned with improving productivity, efficiency and decision-making in global drug development and the regulatory review process as well as public policy issues that relate to these research activities. During his research career, Professor Walker has co-authored over 150 research papers and edited nineteen books in the fields of toxicology, clinical development and regulatory policies.

Professor Walker is a member of a number of academic, professional and industrial committees and sits on the editorial boards of several scientific journals. He is frequently involved in the organization of national and international meetings on key issues that concern the pharmaceutical industry and has lectured extensively throughout Europe, Japan and the U.S.A.